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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/698,223	10/31/2003	Warren L. Starkebaum	P-11296.00	1509

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EXAMINER
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TOY, ALEX B

ART UNIT	PAPER NUMBER
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3739

DATE MAILED: 12/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

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<b>Office Action Summary</b>	<b>Application No.</b> 10/698,223	<b>Applicant(s)</b> STARKEBAUM ET AL.	
	<b>Examiner</b> Alex B. Toy	<b>Art Unit</b> 3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 17 November 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) 12-15 and 18-30 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 1-11, 16 and 17 is/are rejected.
- 7) ☐ Claim(s) 3 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 31 October 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>10/31/03</u> . | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Election/Restrictions*

Claims 18-30 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election of Invention I was made **without** traverse in the reply filed on November 17, 2005.

Applicant's election without traverse of Species II shown in Fig. 2 in the reply filed on November 17, 2005 is acknowledged. Claims 12-15 are also withdrawn from further consideration as being drawn to nonelected Species IV (Fig. 4), Species V (Fig. 5), Species IX (Fig. 9), and Species VII (Fig. 7), respectively.

In summary, claims 12-15 and 18-30 are withdrawn from further consideration. Claims 1-11 and 16-17 are examined.

### *Claim Objections*

Claim 3 is objected to because of the following informalities: "The" should be the first word of the claim. Appropriate correction is required.

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 6-11, and 16-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Edwards (U.S. Pat. No. 6,254,598 B1).

Regarding claim 1, Edwards discloses the steps of:

determining a first acid level of a patient with a hyperacid condition;

ablating tissue within a stomach with an ablation probe sized to fit the stomach to inhibit the production of acid by the tissue; and

determining a second acid level of the patient following a period of time after ablation.

Since the device of Edwards includes a pH monitoring catheter (col. 5, ln. 65-67), it inherently determines a first and second acid level as claimed. Since the device of Edwards ablates the stomach (col. 5, ln. 30-33), it inherently inhibits the production of acid by the tissue when it ablates the stomach. Therefore, since the device of Edwards meets the steps of claim 1, the Office maintains that Edwards inherently discloses a method for reducing stomach acid secretion.

Regarding claim 2, Edwards discloses the method of claim 1, wherein determining the first acid level comprises monitoring acid reflux levels with an esophageal pH monitor. Since Edwards discloses a pH monitor that is used in the esophagus (col. 5, ln. 65-67), it is inherently capable of monitoring acid reflux levels to determine a first acid level.

Regarding claim 3, Edwards discloses the method of claim 1, wherein the first and second acid levels are first and second esophageal acid levels. Since Edwards

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discloses a pH monitor that is used in the esophagus (col. 5, ln. 65-67), it inherently measures esophageal acid levels.

Regarding claim 4, Edwards discloses the method of claim 1, wherein inhibiting the production of stomach acid comprises reducing an amount of acid refluxed into an esophagus of the patient. Since ablation of the stomach inherently inhibits the production of stomach acid, it would inherently reduce the amount of acid that is available to be refluxed into an esophagus of the patient.

Regarding claim 6, Edwards discloses the method of claim 1, wherein ablating tissue comprises ablating at least a portion of a mucosal lining of the stomach. Since the device of Edwards ablates the inside of the stomach (col. 5, ln. 30-33), it must inherently ablate at least a portion of a mucosal lining of the stomach (col. 7, ln. 22-42 and Figs. 2d-2e).

Regarding claim 7, Edwards discloses the method of claim 1, wherein ablating tissue comprises ablating cells that produce stomach acid. Since the device of Edwards ablates the stomach (col. 5, ln. 30-33), it must inherently ablate cells that produce stomach acid (col. 7, ln. 22-42 and Figs. 2d-2e).

Regarding claim 8, Edwards discloses the method of claim 1, wherein ablating tissue comprises:

inserting an ablation probe to the stomach via an esophagus of the patient;

moving the ablation probe to a position proximate to a mucosal lining of the stomach; and

activating the ablation probe to ablate at least a portion of the mucosal lining (col. 5, ln. 30-33, col. 7, ln. 22-42 , and Figs. 2d-2e).

Regarding claim 9, Edwards discloses the method of claims 1 and 8, where the ablation probe comprises at least one of a radio frequency, laser, ultrasonic, microwave, thermal, chemical, mechanical, and cryogenic ablation probe (col. 6, ln. 45-49).

Regarding claim 10, Edwards discloses the method of claims 1 and 8, wherein activating the ablation probe comprises delivering energy to the mucosal lining of the stomach via the ablation probe (see the rejections of claims 8 and 9).

Regarding claim 11, Edwards discloses the method of claims 1 and 8, wherein the ablation probe comprises at least one electrode and wherein activating the ablation probe comprises delivering electrical current to the mucosal lining of the stomach via the electrode (see the rejections of claims 8 and 9).

Regarding claim 16, Edwards discloses the method of claims 1 and 8, wherein the catheter comprises an endoscope (col. 5, ln. 65-67).

Regarding claim 17, Edwards discloses the method of claim 1, further comprising ablating additional stomach tissue based on a comparison of the second esophageal acid level to the first esophageal level. Since the device of Edwards includes a pH monitoring catheter (col. 5, ln. 65-67), it inherently ablates additional stomach tissue based on a comparison of the second esophageal acid level to the first esophageal level.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Edwards ('598).

Regarding claim 5, Edwards discloses the method of claim 1. The claim differs from Edwards in calling for the period of time after ablation to comprise one week. Edwards includes a pH monitoring catheter (col. 5, ln. 65-67) but is silent with respect to any time periods. At the time the invention was made, however, it would have been obvious to one of ordinary skill in the art to measure pH at any desirable time after the ablation procedure.

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**Conclusion**

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

US 20040236381 A1	US-PGPUB	Dinsmoor, David A. et al.
US 20030153905 A1	US-PGPUB	Edwards, Stuart Denzil et al.
US 6006755 A	USPAT	Edwards; Stuart D.
US 6405732 B1	USPAT	Edwards; Stuart D. et al.
US 6258087 B1	USPAT	Edwards; Stuart et al.
US 20020065512 A1	US-PGPUB	Fjield, Todd et al.
US 6535764 B2	USPAT	Imran; Mir A. et al.
US 5738683 A	USPAT	Osypka; Peter
US 20030009095 A1	US-PGPUB	Skarda, James R.
US 20040215180 A1	US-PGPUB	Starkebaum, Warren L. et al.
US 20020103424 A1	US-PGPUB	Swoyer, John M. et al.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alex B. Toy whose telephone number is (571) 272-1953. The examiner can normally be reached on Monday through Friday, 8:00 AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C.M. Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



LINDA C. M. DVORAK  
SUPERVISORY PATENT EXAMINER  
GROUP 3700



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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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12/12/05